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Part V

Consumer Product Safety Commission

Urea-Formaldehyde Foam Insulation; Proposed Notice to Purchasers

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1405

Urea-Formaldehyde Foam Insulation; Proposed Notice to Purchasers

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to require manufacturers of urea-formaldehyde (U.F.) foam insulation to give specified performance and technical information to prospective purchasers and purchasers to alert them about the possible adverse health effects associated with the release of formaldehyde gas from the product after it is installed in residences. Based on consumer complaints and other available medical and scientific information, the Commission believes that consumers who are exposed to formaldehyde gas may suffer eye, nose, and throat irritation, coughing, shortness of breath, skin irritation, nausea, headaches, and dizziness. People with respiratory problems or allergies, especially persons who are allergic to formaldehyde, may suffer more serious reactions. The Commission believes that this rule will ensure that consumers are given accurate safety-related information concerning the product, so that they may make informed choices in purchasing the product.

DATES: Under the proposal, manufacturers of urea-formaldehyde foam insulation would have to comply with this disclosure requirement for sales to consumers or for contracts of sale that are presented to consumers beginning six weeks after publication of a final regulation. Written comments on this proposal must be submitted to the Commission on or before August 11, 1980.

ADDRESS: Written comments, preferably in five copies, should be submitted to the Secretary, Consumer Product Safety Commission, Washington, D.C., and should be titled *U.F. Foam Insulation, Section 27(e) Proposal.*

All materials the Commission has that are relevant to this proceeding, including any comments that may be received on this proposal, may be seen in, or copies obtained from, the Office of the Secretary, Third Floor, 1111 18th Street, N.W., Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Harry Cohen, Program Manager, or Nick Marchica, Project Manager, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492–6453.

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is proposing this rule because it is concerned about adverse health effects associated with the release of formaldehyde gas from urea formaldehyde (U.F.) foam insulation after it is installed in homes. As described in section D(1) of this preamble, the Commission has received over 1000 consumer complaints of adverse health effects from the release of formaldehyde gas from U.F. foam insulation.

The range of severity of reported reactions varies from short term discomfort to chronic impairment, such as the loss of visual acuity, reduction in lung function, and sensitization to other sources of formaldehyde. In some cases consumers were hospitalized or forced to vacate their homes. Based on this information and other medical and scientific information discussed in section D(2) of this preamble concerning the human health effects of exposure to formaldehyde gas, the Commission believes that formaldehyde released from U.F. foam insulation can cause serious illness in humans. The most common reactions are eye, nose, and throat irritation, coughing, shortness of breath, skin irritation, nausea, headaches, and dizziness. Persons with respiratory problems or allergies, especially persons who are allergic to formaldehyde, can suffer more serious reactions. As discussed in section M of this preamble, the Commission has preliminarily determined that there is an unreasonable risk of injury association with U.F. foam insulation that is sold by manufacturers without the information in the proposed regulation.

The Commission staff learned of possible health problems associated with U.F. foam insulation as early as 1976. In October, 1976, the Metropolitan Denver District Attorneys' Consumer Office filed a petition under section 10 of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2059, requesting the Commission to develop a safety standard under section 7 of the CPSA, 15 U.S.C. 2065, for certain types of home insulation products, including U.F. foam insulation. The petitioner claimed that there is an unreasonable risk of injury of irritation and poisoning associated with UF foam insulation. After considering information compiled by the Commission staff, on March 5, 1979 the Commission decided to defer a decision on the part of the petition relating to U.F. foam insulation and instructed the Commission staff to evaluate additional information on possible means of addressing this alleged unreasonable risk of injury (44 FR 12080).

After gathering additional information, on November 8, and 9, 1979 the Commission staff briefed the Commission on the status of work concerning formaldehyde toxicity and U.F. foam insulation. As a result of these briefings, the Commission decided to hold public hearings to obtain additional information on safety and health problems associated with U.F. foam insulation (44 FR 69578, December 3, 1979). The Commission held public hearings in Portland, Oregon; Atlanta, Georgia; Minneapolis, Minnesota; and Hartford, Connecticut from December 1979 through February, 1980.

Consumers, industry representatives, state and local government officials, scientists, and others testified at the hearings as to their experiences with U.F. foam insulation and formaldehyde. Many of these people expressed support for a written notification of safety-related information to consumers. Based on the information obtained in these hearings as well as the consumer complaints and medical and scientific information described in this notice, the Commission has decided it is important that consumers be given technical and performance information concerning the potential release of formaldehyde from U.F. foam insulation installed in homes. The Commission believes that this technical and performance information related to safety should be provided to consumers before the insulation is installed so they can make an informed choice about its use. Therefore, the Commission is proposing the regulation below.

The Commission would like to emphasize that the regulation proposed here may be followed by further Commission action. The regulation could be replaced or supplemented by other regulations, such as a standard for the product or a ban of the product, if the Commission determines that other regulations are necessary to protect the public. The Commission staff intends to complete research projects concerning the release of formaldehyde gas this summer, and expects to brief the Commission this fall on the need, if any, for additional regulatory action.

B. Description of the Proposal

The Commission would issue the proposed regulation under section 27(e) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2076(e)). This section of the act authorizes the Commission to require manufacturers of consumer products to provide the Commission

with such performance and technical data related to performance and safety as may be required to carry out the purpose of the act. Section 27(e) also authorizes the Commission to require manufacturers of consumer products to give notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser for purposes other than resale, as it determines necessary to carry out the purposes of the act. As provided in section 2(b) of the CPSA (15 U.S.C. 2051(b)), two purposes of the act are to protect the public against unreasonable risks of injury associated with consumer products and to assist consumers in evaluating the comparative safety of consumer products.

The proposal would require manufacturers of U.F. foam insulation to provide specified performance and technical data about the product to prospective purchasers of the product for use in homes and to purchasers of the product for use in homes. Manufacturers must do this by giving the consumer a written notice before the U.F. foam insulation is installed. The contents of the notice are prescribed in § 1405.4(b).

Proposed § 1405.1(a) provides that this rule applies only to insulation for use in residences. As proposed, the regulation would not apply to insulation that is installed in commercial buildings, recreational facilities, schools, and other public buildings where consumers may be exposed to formaldehyde gas released from the product. The Commission has limited the proposal in this manner since most of the complaints the Commission has received to date concern homes or residences. At the present time the Commission believes that the information in the written notification would be of greatest benefit to consumers who may purchase the product for installation in homes or residences. During the public hearings, the Commission received testimony from consumers indicating a need for this information.

The Commission has also not extended the application of the proposed regulation to U.F. foam insulation that is sold to builders or contractors for installation in homes that are then sold to consumers. In addition, the Commission has not extended the application of the proposed regulation to provide for notification of subsequent purchasers of homes in which U.F. foam insulation has already been installed. The Commission has not extended the application of the proposed regulation in these areas since the Commission does not believe that section 27(e) of the Act provides an effective means of requiring notification to consumers in these situations.

The proposed regulation, at § 1405.4(a) provides that the written notice must appear on the contract of sale. If the manufacturer does not present a written contract of sale to the prospective purchaser or purchaser, then the notice must appear on a receipt of the transaction, or on a document relating to a credit transaction that gives the seller a security interest in the consumer's real property. If the manufacturer does not present a written contract, receipt, or document related to a credit transaction, then the notice must appear on a separate piece of paper. Regardless of where the written notice appears, it must be presented to the consumer before the U.F. foam insulation is installed.

By requiring the notice to be part of the contract of sale or part of the receipt of the transaction, where there is no contract of sale, the Commission would be ensuring that many prospective purchasers receive the disclosure notice at the beginning of the three day period for cancellation of sales under the Federal Trade Commission's (FTC) trade regulation rule on door-to-door sales (16 CFR Part 429). In a door-to-door sale, the FTC rule gives the consumer the right to cancel the sale at any time within three business days after the date of the transaction indicated on the contract or receipt. Based on informal consultation with the FTC staff, the Commission staff believes that many sales of U.F. foam insulation would be considered door-to-door sales under the FTC's trade regulation rule.

If the notice is part of a document related to a credit transaction giving the seller a security interest in the consumer's real property, then the Consumer Credit Protection Act (15 U.S.C. 1635) and the regulations established by the Federal Reserve Board under that act at 12 CFR § 2269 require a cancellation period similar to that provided by the FTC.

Section 1405.4(c) provides that the notice must appear prominently and conspicuously, and must appear on the same page as the signature of the purchaser and before the signature of the purchaser, if one is provided. Section 1405.4(d) further describes the size and appearance of the notice.

Section 1405.4(e) provides that manufacturers may use any type of a written notice, including one which is pressure sensitive or glued-on, provided the notice is made in such a manner that it will remain attached to the contract of sale, receipt, document related to a credit transaction, or separate piece of paper.

As provided by § 1405.4(f), manufacturers who provide a prospective purchaser or purchaser with any oral or written statement that negates or disclaims the notification will not be considered to have complied with the regulation.

C. Physical Characteristics of U.F. Foam Insulation

(1) *Description of the product and the release of formaldehyde.*

U.F. foam insulation is a cellular plastic product used as a thermal insulation material. The product is manufactured at the job-site by feeding, generally, pressurized air along with two liquid chemicals—a urea-formaldelhyde based (or urea-based) resin and a foaming agent—through a foaming equipment system. The product that results from this reactive mixture has a shaving cream-like consistency and is usually pumped through relatively small holes into the walls of standing structures. After the U.F. foam insulation is inside the wall, the insulation becomes firm or self-supporting. Formaldehyde that has not reacted with other chemicals after installation can eventually be relased as formaldehyde gas. The likelihood of release of formaldehyde depends on factors such as temperature, humidity, foam formulation, architectural considerations, and installation techniques.[1]

Under a contract for the U.S. Department of Energy, the University of Iowa has conducted quantitative research concerning the release of formaldehyde from U.F. foam insulation.[2]

In this study, three commercial U.F. foam insulation materials were foamed and exposed to different temperature and humidity conditions within controlled environmental chambers. This research indicates that formaldehyde emission from U.F. foam insulation can occur over long periods of time after the product is installed.

Evaluation of this research together with general information and technical data presented by Dr. C. B. Meyer of the

[1] NBS Technical Note 946, "Urea-Formaldehyde Based Foam Insulations; An Assessment of their Properties and Performances", Rossiter, Mathey, Burch, and Pierce, July, 1977.

[2] "Problems Associated with the Use of Urea-Formaldehyde Foam for Residential Insulation Part I: The Effects of Temperature and Humidity on Formaldehyde Release from Urea-Formaldehyde Foam Insulation", Long, Pierson, Brennan, Frank, and Hahne, ORNL/SUB-7559/1, U.S. Department of Energy Contract W-7405-eng-26, September, 1979.

University of Washington,[3] shows that: (1) U.F. foam insulation will release a measurable amount of formaldehyde after it is manufactured; and (2) U.F. foam insulation may release formaldehyde gas into the home for an indefinite period of time after installation.

(2) *Possible remedies for problems associated with formaldehyde release.*

Information presented in the public hearings and other information the Commission staff has obtained directly from manufacturers, private consultants, and consumers, indicates that several remedial measures have been used in attempts to correct problems associated with formaldehyde release for U.F. foam insulation. The measures include the following:

- Ventilation (opening doors and windows).
- The use of impregnated charcoal in furnace or air conditioning filters.
- The evaporation of household ammonia in closed and overheated rooms, to neutralize formaldehyde, followed by ventilation.
- Injecting ammonia into the insulation through holes in walls to neutralize formaldehyde.
- Spraying air filters or floors with a specified odor absorbent provided by the manufacturer.
- Using a "masking agent" available from the manufacturer.
- Applying vinyl wall paper or a low permeability paint to interior walls.
- Removal of all or a portion of the insulation from the home.

Although many manufacturers claimed that they had successfully used these remedial measures in many instances, no studies have been done which show that the measures will reliably control the release of formaldehyde gas. The Commission has information obtained from in-depth injury investigations and testimony presented at the public hearings [3a] showing that in some instances, the more simple remedial measures, short of removing the insulation from the walls of the home, do not adequately control the release of formaldehyde gas. The Commission has received reports that in some instances complaints of formaldehyde gas have continued even after the U.F. foam insulation has been removed from the home.

(3) *Recommendations concerning the proper application of U.F. foam insulation.*

Most manufacturers of U.F. foam insulation recommend that the product be installed only in exterior walls and not be installed in attics, ceilings, or interior walls (walls that do not have one side exposed to the outside environment), since application in these areas increases the potential for the release of formaldehyde gas into the home. In meetings with the Commission staff and in testimony at the Commission's public hearings, representatives of NAUFIM (National Association of Urea Foam Insulation Manufacturers) have recommended that the product not be installed in these applications.[3b] Manufacturers and the Commission staff recommend against applying the product in interior walls, since one side of the wall should be exposed to the exterior environment to provide sufficient ventilation to allow the water and formaldehyde vapor present in the foam to escape.

The Department of Energy (DOE) recently proposed installation standards for U.F. foam insulation (44 FR 75956, December 21, 1979). Although the DOE installation standards are not the basis for the regulation proposed here, the DOE proposed standards would not permit the application of U.F. foam insulation in ceilings since: (1) U.F. foam has been shown to deteriorate under high temperature and high humidity conditions frequently found in attics, (2) formaldehyde gas is denser than air, so that gas liberated by the foam may invade the living space below and pose a health hazard to the occupants; and (3) the moisture in the product may damage the ceiling. For similar reasons, the Department of Housing and Urban Development (HUD), in its Use of Materials Bulletin No. 74, also recommends against applying the product in attics and ceilings. In Technical Note 946, the National Bureau of Standards (NBS) recommends against applying the product in attics and ceilings for reasons similar to those explained by DOE, as well as the possibility of excessive shrinkage of the U.F. foam insulation.

D. Potential Adverse Safety and Health Effects

(1) *Information from investigations of consumer complaints.*

As of March 15, 1980 the Commission has received over one thousand complaints of adverse health effects from the release of formaldehyde gas from U.F. foam insulation. Approximately 585 complaints came directly to the Commission. The remainder are consumer complaints that several states have sent to the Commission. The Commission staff estimates that about 2600 persons suffered adverse health effects for the one thousand complaints received so far.

The Commission staff has conducted in-depth investigations for 218 of the complaints reported directly to the Commission. The in-depth investigations of these complaints show a range of severity of reported reactions varying from short term discomfort to chronic impairment, such as the loss of visual acuity, reduction in lung function, and sensitization to other sources of formaldehyde. Eleven persons in five households reported being sensitized to formaldehyde, meaning that persons suffer increasingly severe allergic reactions to continued exposure to formaldehyde. Twenty-eight persons were hospitalized following installation of the insulation. Most of the hospitalizations were for respiratory distress. The most common reactions reported by consumers are eye, nose, and throat irritation, coughing, shortness of breath, skin irritation, nausea, headaches and dizziness.

According to the in-depth investigations, reactions to formaldehyde developed at times ranging from the day the insulation was installed to more than two years after installation. One out of five health problems reported to the Commission began two months or more after the insulation was installed.

Thirty-seven of the in-depth investigations show that there were medical diagnoses linking the reported symptoms to formaldehyde. In many other cases, consumers sought medical treatment but did not receive a specific medical diagnosis implicating formaldehyde. The medical diagnosis of illness resulting from exposure to formaldehyde is difficult, since many of the reactions resemble symptoms associated with flu, colds, and asthma. Unless the consumer specifically mentions U.F. foam insulation the physican may often be uncertain as to the cause of the medical symptoms. In some cases the examining physician advised the patients to vacate their homes even though the medical diagnosis did not specifically mention formaldehyde.

According to the in-depth investigations, the consumer's symptoms often disappear when the consumer leaves the home and reappear after the consumer returns to the home. Measurements of free formaldehyde in air samples are available for 58 of the homes in the in-depth investigations. Twenty-two of the tests reportedly used

[3] *Urea-Formaldehyde Resins*, Meyer, Addison-Wesley Publishing, Inc., 1979.

[3a] Portland Tr. pp. 79, 93, 115–116, 137, 252–254, 263–264, 283; Atlanta Tr. pp. 39, 107–108, 110, 184–187; Hartford Tr. pp. 68–69, 105–106, 147–148, 249–254, 410, 477, 509.

[3b] Portland Tr. p. 52.

in the National Institute for Occupational Safety and Health (NIOSH) procedure for air collection and laboratory analysis. Ten of those measurements (45.4 percent) were over 1 ppm. (Levels of formaldehyde exceeding 1 ppm are within the range that the scientific studies described below have shown that people suffer adverse physical effects.)

The in-depth investigations also help to establish that U.F. foam may continue to release formaldehyde gas long after installation. In twelve of the homes where air measurements were made using the NIOSH test procedures, the insulation was at least 6 months old at the time the measurements were made. In five of these twelve homes, the level of formaldehyde gas was over 1 ppm.

In 68 of the in-depth investigations the families reported that they had to vacate either all or part of their homes or were unable to move into a new home because of the effects of the U.F. foam insulation. Forty of these families reported that they had left their homes for 60 days or more, or were still out of their homes when interviewed.

(2) *Human health effects resulting from exposure to formaldehyde based on medical and scientific literature.* The National Academy of Sciences (NAS) recently completed work on a contract with the Commission to determine whether there is a tolerable level of formaldehyde in air of homes. After gathering and critically evaluating all pertinent scientific literature, the Committee on Toxicology, a panel of expert toxicologists established by NAS, concluded that on the basis of available data there is no population threshold for the irritant effects of formaldehyde in humans. The Committee found that information from controlled human studies and complaint related investigations suggest that, even at extremely low airborne concentrations, a proportion of the population will respond with some irritation. The Committee recommended that formaldehyde be kept at the lowest practical concentration in indoor residential air.[4]

Studies of human exposure to formaldehyde have generally been either controlled exposure studies, home exposure studies or occupational exposure studies. In the controlled exposure studies, healthy young volunteers were subjected to formaldehyde concentrations of 0.03–4.0 ppm. These volunteers experienced, in general, discomfort and irritation of the eye, nose, and throat, ranging from mild to severe as well as an increase in eye blinking rate and a decrease in nasal mucus flow rate.[5] The severity of these responses and the numbers of subjects affected were dependent on the concentration and duration of exposure.

Under less controlled conditions, case studies of formaldehyde exposure in mobile homes and U.F. foam insulated homes at concentrations ranging from 0.03–10 ppm produced an even greater variety of adverse health affects.[6] In those mobile homes where consumers had complaints, 90 percent of the formaldehyde concentrations measured were below 1 ppm. The reactions included drowsiness, nausea, headaches; as well as irritation of the eye, nose, and respiratory track.[7] In a group of homes with U.F. foam insulation with levels less than 0.5 ppm formaldehyde, consumers reported eye irritation, upper respiratory symptoms, headaches and skin problems. Disturbances of the gastro-intenstinal tract were also reported when exposure concentrations were higher than 0.5 ppm.[8]

Persons exposed to formaldehyde in occupational situations have experienced eye, nose, and throat irritation (tearing, sneezing, coughing, dry and sore throat) as well as decreased sense of smell and skin irritation caused by the formaldehyde.[9]

The scientific literature also contains reports of headaches, dizziness, increased thirst, lethargy, irritability, disturbed sleep, inability to concentrate, moodiness, paranoia, crying without cause, and a crawling sensation of the skin.[10] In addition, asthmatic reactions have been observed from exposure to formaldehyde.[11] Continued exposure for long periods can also lead to chronic changes of the respiratory tract, such as hypertrophic, subrophic, or atrophic rhinitis and bronchitis.[12]

The scientific literature indicates that repeated exposure to formaldehyde liquid can cause sensitization in certain individuals. When exposed to formaldehyde these sensitized persons may exhibit allergic dermatitis[13] or mild to severe asthmatic reactions.[14] There

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[4] Committee on Toxicology, National Academy of Sciences, "formaldehyde—An Assessment of Its Health Effects", (March, 1980).

[5] Anderson, I. (1979.) Formaldehyde in the indoor environment-health implications and the setting of standards. In Fanger, P.O. and Valbjorn, O: *eds.* Indoor climate: Effects on human comfort, performance and health in residential, commercial and light-industry buildings. Proc. of the First International Indoor climate symposium, Copenhagen, August 30–September 1, 1978. pp. 65–87.

Weber-Tschopp, A., Fischer, T., and Grandjean, E. (1977.) Reizwickungen des Formaldehyde (HCHO) auf Menschen. Irritating effects of formaldehyde on men. Int. Arch. Occup. Environ. Health 39: 207–218.

[6] Breysse, P.A. 1977. Formaldehyde in mobile and conventional homes. Environmental Health Saf. News. 26 (1–6) 20 p

Sardinas, A.V., Most, R.S., Guilletti, M.A., and Honchar, P. 1979. Health effects associated with Ureaformaldehyde foam insulation in Connecticut. J. Environ. Health. 41: 270–272.

Gary, V.F., Oatman, L., Pleuss, R. and Gray, D. 1980. Formaldehyde in the home. Some environmental disease perspectives. Minnesota Med. 63: 107–111.

[7] Breyss, (1977) *Ibid.*

[8] Sardinas, (1979) *Ibid.*

[9] Weger, A. (1927). Thalamic sympton complex with formalin intoxication. Z. Ges. Neur. Psych. 111:370–82. (Discussed in NIOSH Report on recommended standard for exposure to formaldehyde, December, 1976.)

Yefremov. G.G., The state of the upper respiratory tract in formaldehyde production employees. Zh. Ushn. Nos. Gorl. Bolazn 30:11–15, 1970.

Gamble, J.F.; McMichael, A.J.; Williams, T.; and Battigelli, M. (1976) Respiratory function and Symptoms: An environmental-Epidemiological study of rubber workers exposed to phenol-formaldehyde type resin. Am. Ind. Hyg. Assoc., J., 37:499–513.

[10] Weger, (1927) *Ibid.*

Kamchatnov, V.P. and Gayazova, S.S. (1971). Temperature and asymmetry in workers exposed to formaldehyde vapor. Hyg. and San. 36:286–87

Morrill, E.E. (1961). Formaldehyde exposure from paper process solved by air sampling and current studies. Air. Cond. Heat. Vent. 58:94–95. (Discussed in NIOSH report on recommended standard for exposure to formaldehyde, December, 1976.)

Ahmed, I. and Whitson, T.C. (1973). Formaldehyde: How much of a hazard? Ind. Med. and Surg. 42:26–27. (Discussed in NIOSH report on recommended standard for exposure to formaldehyde, December, 1976.)

[11] Ludwig, (1935). Acute formaldehyde bronchiolitis in workmen handling artificial resin. Samml. Vergiftunsfallen. 6:227–30. (Discussed in NIOSH report on recommended standard for exposure to formaldehyde, December, 1976.)

Helwig, N. (1977). Occupational formalin asthma. Dtsch. Med Woch 102:1612–13.

Paliard, F., Roche, L. Exbrayat, C., and Sprunck, E. (1949). Chronic asthma due to formaldehyde. Arch. Mal. Prof. 10:528.

Turiar, C. (1952). Asthma through sensitivity to formaldehyde. Soc. Franc. d'Allergic. Seance du 18. Nov. (Discussed in NIOSH report on recommended standard for exposure to formaldehyde, December, 1976.)

Nova. Turaine (1957) Asthma from formaldehyde. Arch. Mal. Prof. 18:293. (Discussed in NIOSH report on recommended standard for exposure to formaldehyde, December, 1976.)

Sakula, A. (1975). Formalin asthma in hospital laboratory staff. Lancet: 2:816.

Hendrick, D.J. and Lane, D.J. (1977). Occupational formalin asthma. Br., J. Ind. Med 34:11–18.

[12] Yefremov. (1970) *Ibid.*

Kratochvil. I. (1971). The effect of formaldehyde on the health of workers employed in the production of crease resistance ready made dresses. Pr. Lck. 23:374–75. (Abstract)

[13] Horsfall, F. D. (1934). Formaldehyde hypersensitiveness—An experimental study. J. Imunol. 27:569–81.

Pirila, V.; and Kilpio, O. (1949). On dermatitis caused by formaldehyde and its compounds. Am. Med. Intern. Fenn. 38:38–51. (Discussed in NIOSH Report on recommended standard for exposure to formaldehyde, December, 1976.)

Hovding, G. (1969). Occupational dermatitis from pyrolysis products of polythene. Acta Derm. Venereol. 49:147–49.

[14] Sakula, (1975) *Ibid.*

Hendrick and Lane, (1977) *Ibid.*

are indications that some of the sensitized individuals may develop increasingly severe reactions upon continued exposure to formaldehyde.[15] It is estimated that 4.5 to 7.8 percent of the population may be sensitized to formaldehyde.[16]

Persons who have a history of allergic [17] or inflammatory diseases are generally considered to be more prone to the development of new chemical allergies, including an allergy to formaldehyde.[18] Although the causes for this increased sensitivity have not been determined, these factors could be related to (1) genetic factors controlling the allergic process, (2) the allergic process itself, or (3) the likelihood that one of the allergenic products to which the individual was exposed either contained of produced formaldehyde. Persons who have asthma or other respiratory problems are likely to experience more serious reactions when exposed to formaldehyde.[19] Based on this information, the Commission believes that persons who have respiratory problems or allergies, especially persons who are allergic to formaldehyde, are likely to experience more serious physical reactions when exposed to formaldehyde gas released from U.F. foam insulation.

The in-depth investigations and the scientific and medical literature discussed above indicate that exposure to formaldehyde can produce various illnesses in humans.[20] The extent and duration of the illnesses depend on the degree of the exposure and the physical condition of the victim. In the case of brief contact, formaldehyde gas initially and commonly causes symptoms such as nasal irritation and congestion, stuffiness, watering and burning of the eyes, sneezing, sinus pain, coughing, irritation, dryness, and burning of the throat. In addition, exposures of short duration have produced headaches, dizziness, nosebleeds, and nausea. Although the symptoms of exposure to formaldehyde are similar to those associated with colds, flu, and allergies, the symptoms are generally transient, meaning that the symptoms continue during exposure but are partially or completely alleviated when the person is removed from the site of exposure.

Repetitive exposure to formaldehyde primarily affects the respiratory system. The illnesses associated with repetitive exposure to formaldehyde that have been reported are caused by chronic irritation. These illnesses include: difficulty in breathing (asthma-like symptoms), chronic rhinitis and pharyngitis, chest pains, persistent cough and "chest congestion". Exposures of sufficiently prolonged duration may markedly aggravate existing pulmonary pathology and could initiate severe pulmonary illnesses.[21]

(3) *Long term health effects resulting from formaldehyde exposure.* In a two-year long-term inhalation study sponsored by the Chemical Industry Institute for Toxicology (CIIT) that is scheduled for completion in June, 1980, rats and mice have been exposed to 2, 6, and 15 ppm of formaldehyde gas. On October 16, 1979, representatives of the formaldehyde Institute, and industry trade association, informed the Commission that preliminary test results from this study indicated that rats exposed to 15 ppm of formaldehyde gas developed squamous cell carcinomas.

By January 1, 1980 a total of 20 female and 17 male rats had developed squamous cell carcinomas at the 15 ppm exposure level. Carcinomas first appeared after 12 months of exposure. In a random sample of rats selected for sacrifice and pathological examination after 18 months of exposure at the dose level of 15 ppm, 20 percent of the rats had developed squamous cell carcinomas. So far, the laboratory mice tested have not developed cancer. On January 17–18, 1980, an IRLG (Interagency Regulatory Liaison Group) task force on formaldehyde visited CIIT to obtain additional information concerning the long term study and to verify the findings of CIIT. The task force included pathologists from the Commission, the National Institute of Environmental Health Sciences (NIEHS), the Department of Energy, the Evironmental Protection Agency, and the National Cancer Institute. In a report prepared in February, 1980, the group of pathologists concurred, in general, with the CIIT observations, diagnoses, and interpretations.

The results of several other long term animal studies to determine the teratogenic and carcinogenic potential of formaldehyde have been negative.[22] However, one study has suggested that formaldehyde may have a co-carcinogenic potential, meaning that formaldehyde may increase the incidence of tumors when combined with a different substance that is known to be a carcinogen.[23] At the present time there is a lack of epidemiological data concerning cancer in humans that may be caused by formaldehyde.

The human health implications of these studies are not yet known. Recently, the Commission, in conjunction with the National Toxicology Program (NTP) formed a panel of federal scientists to help evaluate the existing data on carcinogenicity and assess their implications for humans. The panel is now considering available information and hopes to conclude its activities on July, 1980.

The Commission has also requested that NTP initiate additional studies to further define formaldehyde toxicity. These studies include assays for carcinogenicity, nutagenicity, and teratogenicity. Nutagenicity work currently being conducted at NCI includes AMES-type testing, malignant transformation, and unscheduled DNA

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[15] Shellow, N., and Altman, A. T. (1966). Dermatitis from formaldehyde resin textiles. Arch. Dermatol. 94:799–801.

Skogh, M. 1959. Axillary exzema in women, a syndrome. Acta Derm. Venereol. 39:369–371. (Discussed in NIOSH Report on recommended standard for exposure to formaldehyde. December, 1976.)

Breysse, (1977) *Ibid.*

[16] Marzulli, F. N. and Maibach, H. I. (1974). The use of graded concentrations in studying skin sensitizers: Experimental contact sensitization in Man. Food and Cosmetics Toxicology. 12:210–227.

[17] As used here and in the notice proposed at section 1405.4(b), persons with allergies are those persons who have a current history of allergic responses to a number of allergens.

[18] Loomis, T. A. (1979) Formaldehyde Toxicity Pathol. Arch. Lab. Med. 103:321–24.

[19] March 26, 1980 memorandum from Albert F. Esch., M.D., Medical Director, CPSC to A. G. Ulsamer, Ph.D., CPSC.

April 18, 1980 memorandum from K. C. Gupta, Ph.D., ESHE, CPSC, to Harry Cohen, OPM, CPSC. Studies in factory workers have shown chronic upper respiratory tract changes. In addition, animal studies have shown increased airway resistance in guinea pigs exposed to formaldehyde.

Yefremov (1970). *Ibid.* and Kratochvil, (1971) *Ibid.*

Amdur, M.O. (1959) the physiological response of guinea pigs to atomospheric pollutants, Int. J. Air Poll. 1:170–83. (Discussed in NIOSH Report on recommended standard for exposure to formaldehyde. December, 1976.)

[20] March 26, 1980 memorandum from Albert F. Esch., M.D., Medical Director, CPSC to A. G. Ulsamer, Ph.D., CPSC.

[21] March 26, 1980 memorandum, Esch. *Ibid.*

[22] Klenitzky, J. S. (1940). On experimental Cancer of Uterine Cervix, Bull, Bio. Expt. Med. 9:3–6. (Discussed in NIOSH Report on recommended standard for exposure to formaldehyde. December, 1976.)

Brendel, R. (1964). Studies on Compatability of hexamethylenetetramine in rats. Arzneimittle-Forsch. 14:51.

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Della Porta, G., Cabral, J. R. and Parmiani, G. (1970). Transplacental Toxicity and Carcinogenesis Studies in Rats with Hexamethylenetetramine (Italian). Tumori *56*, 325–334.

Hurni, H. and Ohder, H. (1973). Reproduction Study with Formaldehyde and Hexamethylenetetramine in Beagle Dogs. Fd. Cosmet. Toxicol. *11*, 459–462.

[23] Dalbey W., and Netteschein, P. (1980). Personal Communication.

synthesis. These additional tests will help the Commission in assessing the preliminary results obtained in the CIIT study.

The proposed notification at section 1405.4(b) does not include a reference to these studies or the possible long-term health effects associated with exposure to formaldehyde. However, in commenting on this proposal, interested persons should take into account the possibility that, based on the assessment of existing information by the panel of federal scientists as well as additional information that is obtained during this rulemaking, the Commission may decide to include information concerning the possible long-term health effects in the notification if the Commission issues a final rule. In this regard the Commission could:

(1) Issue a final regulation without any notification concerning the possible long-term health effects of exposure to formaldehyde.

(2) Issue a requirement for a notification that describes the existing scientific data concerning animal tests.

(3) Issue a requirement for a notification that includes a statement concerning the carcinogenic potential to humans of exposure to formaldehyde.

The Commission requests interested persons commenting on this proposed regulation to address these possibilities. This regulation, if it is issued as a final regulation, could be replaced or supplemented by other Commission regulations if the tests described above concerning the possible long-term effects warrant such action.

E. The Need for the Written Notification

The notification requirement proposed here is needed to help the Commission in carrying out the purposes of the act of protecting the public against unreasonable risks of injury and in assisting consumers in evaluating the comparative safety of consumer products. The notification requirement would accomplish these purposes by ensuring that prospective purchasers and purchasers have accurate information concerning the release of formaldehyde from U.F. foam insulation, so that consumers may make an informed decision in purchasing the product.

The notification is necessary since it would provide all prospective purchasers and purchasers with general information describing the technical and performance aspects of the product and the health reactions that can occur where there are problems associated with the release of formaldehyde from the product. Since some of the physical symptoms that are caused by exposure to formaldehyde gas may be flu-like symptoms, some consumers may not be aware of the relationship between the physical symptoms and the product. This information may help those consumers who purchase the product with the disclosure and later experience reactions to associate the product with the health problems.

The notice should also provide protection for purchasers since the notice provides information concerning persons to contact for assistance, including the consumer's physician. The disclosure also includes technical and performance data describing the safety and health effects of exposure to formaldehyde gas on persons with respiratory problems and allergies, and informs these persons that they may experience more serious reactions than the rest of the populations.

The notification requirement is necessary since many people may be unaware of these facts at the time of the purchase.[24] To the extent that these prospective purchasers read this information and base their purchasing decision on this information, the notification would protect these consumers against the adverse safety and health effects that can result from the release of formaldehyde gas by the product.

The information in the proposed notification requirement would also assist consumers in evaluating the comparative safety of U.F. foam insulation. The proposed notification would ensure that prospective purchasers received accurate safety-related information concerning the product that could be used by consumers in comparing U.F. foam insulation with other types of insulation and in evaluating safety aspects of the types of insulation materials that are available for purchase.

In the process of gathering information concerning problems associated with U.F. foam insulation through public hearings and discussions with manufacturers and consumers, the Commission staff has learned that consumers may not receive information concerning the safety related aspects of the product.[25] At the present time, the Commission believes that safety related information given to prospective purchasers varies from manufacturer to manufacturer, and may vary according to different requirements imposed by various state and local governments.[26] The notification requirement proposed here would help ensure that prospective purchasers and purchasers receive at least a minimum amount of important performance and technical data related to safety and would ensure that consumers receive this information in a uniform manner.

In the Commission's public hearings and in discussions with the Commission staff, manufacturers and installers of U.F. foam insulation, state and local government officials, consumers and others have expressed support for a written notification of safety-related information.[27]

F. Economic Impact

(1) Background

Although U.F. foam insulation has been used in Europe for many years,

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[24] At the Commission's public hearings, the Commission received testimony from several consumers indicating that they received no information or received misinformation from the installer concerning the possible adverse safety and health effects associated with the release of formaldehyde gas from the product: Portland Tr. p. 97; Atlanta Tr. pp. 54, 114–115, 178; Hartford Tr. pp. 73, 108, 154–155, 508, 522.

[25] Nine consumers with complaints concerning their U.F. foam insulation testified that they received no information or received misinformation from the installer concerning the possible adverse safety and health effects associated with the release of formaldehyde gas from the product: (Portland Tr. pp. 73, 108, 154–155, 508, 522).

[26] At the Commission's public hearings the testimony from manufacturers indicated a wide divergence in the extent of the information presented to consumers and the manner of presentation. Some manufacturers stated that they provided an oral statement (Atlanta Tr. pp. 46–48, 216; Minneapolis Tr. p. 249; Hartford Tr. p. 434), other manufacturers indicated that they presented a written notification (Portland Tr. pp. 250–251, Minneapolis Tr. p. 104). One manufacturer indicated that he presented both an oral and written statement (Atlanta Tr. p. 378). One manufacturer stated that his notification varied depending on state requirements (Atlanta Tr. pp. 333–334). Another manufacturer expressed concern that the lack of a uniform requirement would lead some competitors to make unrealistic claims about the performance of their product (Atlanta Tr. p. 293).

[27] At the Commission's public hearings fifteen manufacturers and installers of U.F. foam insulation expressed support for a written notification of safety-related information to consumers. (Portland Tr. pp. 39, 50–51, 250–251; Atlanta Tr. pp. 43, 47–48, 93, 217, 287–288, 293, 324, 333, 341, 378, 383; Minneapolis Tr. pp. 104, 249, 348, 349; Hartford Tr. pp. 92, 434, 465–467, 532–533.

Six state and local officials expressed support for a disclosure to consumers. (Portland Tr. pp. 137, 380; Hartford Tr. pp. 14, 116, 126, 140–141, 404).

Three consumers also expressed support for a disclosure statement. (Portland Tr. pp. 97–98; Atlanta Tr. pp. 114–115; 190).

In addition, a trade association of formaldehyde producers (Portland Tr. pp. 145–146), a consulting and engineering firm (Atlanta Tr. pp. 28–29), a doctor at a children's health center (Minneapolis Tr. pp. 48–49); a national consumer organization (Hartford Tr. p. 336); and a medical doctor at a university (Hartford Tr. p. 502) also expressed support for a disclosure of safety-related information to consumers.

The Commission has also received written comments from consumers, a consumer group, and a state government supporting a disclosure of safety-related information to consumers (cc 14–78–6; cc 14–79–18; cc 14–79–37; cc 14–79–43; cc 14–79–45; cc 14–79–52(L)).

U.S. interest in U.F. foam insulation began when the increased costs of energy in the mid-1970's stimulated consumer demand for residential insulation. Installations of U.F. foam increased rapidly to an industry high in 1977, when increased demand for insulation created shortages for alternative insulating materials.

The primary market for U.F. foam insulation is for sidewall insulation in existing homes. A study conducted for the Commission estimated that 60,000 homes were insulated with U.F. foam in 1975; 170,000 in 1977, and 125,000 in 1978 (later information suggests that the 1978 estimate may have been overstated). Based on information provided by industry sources, the Commission staff estimates that in 1979 there were 60,000 to 70,000 installations of U.F. foam in homes. There has been a definite decline in the number of installations in U.F. foam since 1977. This decline may be due to decreased overall demand for insulation products and resulting increased availability of alternative insulating materials, in addition to adverse publicity related to U.F. foam insulation in some areas of the country.

Installation of U.F. foam in 1980 may increase slightly over 1979 totals, according to industry sources. Perhaps somewhat less than a half million homes have been insulated with U.F. foam since its introduction in this country.

In the United States, there may be 30 or more suppliers of U.F. resins for U.F. foam insulation, although perhaps 85 to 90 percent of the installations use products supplied by the ten largest firms. At the present time, there are probably fewer than 3,000 installers of U.F. foam in the United States. The Commission staff believes that the number of installers is much less than the number of installers in 1977, the peak year for installation of U.F. foam.

The Commission staff estimates that the installed cost of U.F. foam ranges from 70¢ to $1.25 per square foot. For the average home, the cost to consumers may range from $1,050 to $1,875. If it is assumed that the average installed cost is $1 per square foot and 60,000 to 80,000 homes will be insulated with U.F. foam in 1980, consumer expenditures may total $90 to $120 million. The wholesale value of the U.F. resin and foaming agents used in these installations may be about ⅓ of the installed retail value, or $30 to $40 million.

(2) Possible Decrease in Demand

The Commission believes that the major economic impact of the disclosure requirement would be a possible reduction in the total number of installations.[28] Although it is difficult to estimate the decrease in the number of installations that may result from the regulations, the magnitude of the decrease is likely to depend on several factors:

(a) *State and local actions.* In states, such as Connecticut, that have adopted a disclosure requirement similar to that proposed here by the Commission, the Commission's disclosure requirement may not further reduce sales of the product. In states and local governments that have already banned the product, such as Massachusetts, or ban the product in the future, the Commission's disclosure requirement would not further reduce sales where these bans remain in effect.

(b) *Previous public awareness of the possible effects of formaldehyde release.* In some areas of the country, especially where there has been state and local concern about the product, the pubic's awareness of potential problems has been increased. To the extent that potential purchasers are already aware of possible hazards with the product, this may lessen the decrease in demand that could be expected.

(c) *Other factors.* Additional factors that could affect the purchasing decisions of persons presented with the written notification are consumer perceptions of the severity of possible adverse health effects, considerations of the health of existing members of the household (whether any members have respiratory problems or allergies), and the likelihood that adverse health effects may result. The purchasing decision may also be influenced by consumer perceptions of the reputation of the installer, the extent to which previous installations have been successful, and the likelihood of success of remedial measures that may be taken to correct problems, along with the willingness of the manufacturers to undertake such remedial measures. The decision to purchase U.F. foam insulation may also be influenced by consumer expectations of savings in costs to heat or cool their homes as a result of the U.F. foam insulation.

Although the effect of the rule on demand for the product has not been determined at this time, a significant decrease in demand could lead installers to decrease their prices in order to compete with alternative insulation materials. A significant decrease in demand could also affect the availability of U.F. foam insulation, since some installers may decide not to offer U.F. foam insulation.

In the event that consumers decide not to purchase U.F. foam insulation, or if the availability of U.F. foam insulation is reduced, the Commission believes that substitute insulation products, such as cellulose and mineral wool (fibrous glass) insulation, would be available for use in many of the homes that are candidates for insulation with U.F. foam insulation.

(3) Direct Costs of the Written Notification.

The Commission believes that the direct costs of providing the written notification that would be required by this rule would be insignificant. The direct costs will vary from manufacturer to manufacturer, since some manufacturers may revise their contracts of sale and have copies made, while other manufacturers may have the notice printed on a separate sheet of paper and have copies made. In all cases the direct costs of printing the written notification would be insignificant in relation to the purchase price of the product. A report prepared for the Commission staff estimates that the average purchase price of installed foam is 70¢ per square foot. The report estimates that the average outside wall area of a home that is insulated with U.F. foam is about 1,500 square feet, so that the average retail value of a U.F. foam installation was $1,050 in 1979.[29] (In a September 1978 article in the *The Family Handyman,* the estimated installed cost of U.F. foam ranged from 75¢ to $1.25 per square foot. If this estimate is used, then the installed foam would have a retail value ranging from $1,125 to $1,875 if 1500 square feet are insulated.)

(4) Additional Economic Impacts.

One of the purposes of the proposal is to inform consumers with certain existing physical conditions (respiratory

[28] In Connecticut, nine U.F. foam insulation manufacturers have entered an agreement with the state. The agreement requires, among other things, the manufacturers to include in the contract of sale a warning of possible adverse physical effects resulting from the release of formaldehyde. Since the agreement became effective in April, 1979, the manufacturers who entered the agreement reported 430 installations of U.F. foam insulation from April 20, 1979 to November 1979. The number of installations is much lower than the Commission staff's estimate of an average number of installations in Connecticut of 2,500 per year from 1976 through 1978. However, the reduction in the number of installations of the product may have been the result of adverse publicity associated with the Massachusetts ban of U.F. foam insulation. Because of this factor, it is difficult to estimate the effect of the required notification under the Connecticut agreement.

[29] Battelle Columbus Laboratories, "Product/Industry Profile and Related Analysis of Formaldehyde and Formaldehyde-Containing Consumer Products; Part II-Products/Industry Profile on Urea Formaldehyde," December 15, 1978 (Revised February 5, 1979).

problems or allergies) that they may experience more serious reactions if there is a problem associated with the release of formaldehyde gas from the product. This information could reduce the sale of U.F. foam insulation to consumers with respiratory problems or allergies. However, the Commission believes that the proposed rule would result in a greater average utility of the product, since persons more likely to suffer adverse physical effects may not buy the product. If these consumers do in fact refrain from buying the product, this should reduce the total medical and non-medical costs caused by the release of formaldehyde gas from U.F. foam insulation.

G. Effective Date

The Commission proposes that manufacturers of U.F. foam insulation who make sales to consumers or who present contracts of sale to consumers beginning on the date that is six weeks after publication of a final regulation must comply with the requirements of the regulation.

Based on previous experience with notification rules and the flexible means by which manufacturers may present this notification, provided by § 1405.4(e), the Commission staff believes that the proposed effective date would provide sufficient time for manufacturers to design, order, and distribute the written notification that would be required by this regulation. In an informal conversation with the Commission staff, a large manufacturer of U.F. foam insulation agreed that the proposed effective date would provide sufficient time to comply with the regulation. The Commission anticipates that a final rule could be issued by the middle of October, 1980. The six week interval between publication of the final rule and its effective date should be sufficient time in which to comply with the requirements of the regulation.

H. Environmental Considerations

The most important environmental impact of the regulation proposed here, aside from its potential for limiting the number of homes which would otherwise have increased levels of formaldehyde gas, would be in the form of foregone savings in energy consumption for any homes that might not be insulated as a result of the rule. The Commission staff estimates that for every 1,000 homes that are not insulated by U.F. foam or alternative materials, such as mineral wool (including fibrous glass) and cellulose home insulation, the foregone savings in energy consumption may be about 35.3 billion Btu's of gas, with a value of about $101,000 at 1979 gas prices, and about 138,000 gallons of heating oil, with a value of about $138,000. Since relatively few electrically heated houses are thought to have uninsulated walls, there should be little foregone savings in electricity.

At the present time, the Commission staff is not able to estimate the number of residences, if any, that may not be insulated as a result of the notification requirement. However, the Commission staff believes that the foregone annual energy savings will be very small in relation to total residential energy consumption. For 1979, the reported residential gas use was a total of 5,149 trillion Btu's, and total residential revenues of gas utilities were about $14.7 billion. Total residential fuel oil consumption is reportedly 10.5 billion gallons annually for single family residences.

Based on its consideration of the potential environmental impact of the proposal, the Commission concludes that the environment will not be significantly affected and that an environmental impact statement is not necessary. The Commission's regulations for environmental review (16 CFR Part 1021, § 1021.5) provide that labeling rules are normally non-major actions with little or no potential for affecting the environment, so that an environmental review is not normally required. The Commission does not foresee that this notification requirement will become a major action anticipated to affect the environment.

I. Actions by State and Local Governments and Other Federal Agencies Concerning U.F. Foam Insulation

The Commission is aware of the following actions taken by state and local governments and other federal agencies concerning U.F. foam insulation:

(1) The State of Massachusetts has declared U.F. foam insulation to be a banned hazardous substance and has required the removal of U.F. foam insulation from commerce in that state (105 CMR: Department of Public Health 650.020). The Massachusetts ban became effective November 14, 1979. The Massachusetts regulations are currently in litigation, although the ban itself is in effect during this litigation.

(2) The Attorney General's office of the State of Connecticut has entered an agreement with nine members of the U.F. foam insulation industry to resolve complaints concerning adverse physical effects associated with U.F. foam insulation. The Connecticut agreement also requires manufacturers to provide prospective purchasers with a notice concerning possible adverse health effects associated with U.F. foam insulation. On January 1, 1980, the Connecticut Department of Consumer Protection proposed a regulation to require a health warning in all U.F. foam insulation contracts from all manufacturers.

(3) The Office of the Attorney General of the State of Colorado has issued a warning about potential health hazards to consumers who have purchased U.F. foam insulation. Denver County has adopted a prohibition against the use of U.F. foam in new or existing construction.

(4) On December 18, 1979, the Virginia Department of Health issued a Health Hazard Alert on formaldehyde and U.F. foam insulation.

(5) In several state legislatures, bills have been introduced to require a safety related disclosure (New York, Minnesota), to ban or impose a moratorium on the sale of the product (New Jersey, California, Arizona, West Virginia, New Hampshire, Maryland), or to set performance requirements limiting formaldehyde emission (Minnesota, California).

(6) The Department of Housing and Urban Development (HUD) has issued a Use of Materials Bulletin (UMB #74 for U.F. foam insulation. UMB #74 explains the conditions under which HUD will accept U.F. foam insulation and stipulates certain limitations for its use.

(7) On December 21, 1979, DOE reproposed material and installation standards for U.F. foam insulation under the Residential Conservation Service (RCS) Program established by Title II, Part 1 of the National Energy Conservation Policy Act (NECPA), Pub. L. No. 95–619 (44 FR 75956). The DOE standard, at § 456.810(d)(11)(ii) contains the following proposed warning that would be printed for manufacturers to present to residents prior to the installation of U.F. foam insulation:

> **Caution.**—Under some conditions Urea Formaldehyde insulation may cause the release of formaldehyde gas into living areas, and the development of adverse health effects. Continued exposure to formaldehyde can cause nausea and vomiting, respiratory difficulties, headaches, eye irritation, and allergic reactions. Such symptoms may develop anywhere from a few days to more than six months after the gas is released.

The Commission has submitted oral and written comments to DOE concerning the proposed standards. At the present time, DOE has not decided whether to issue final standards for the product. However, DOE staff have informally advised the Commission staff that in the event the Commission decides to issue a final disclosure

requirement, DOE would suspend any warning requirement issued by DOE.

J. Possible Effect of This Regulation on State and Local Government Actions

Section 26(a) of the act (15 U.S.C. 2075(a)) provides that where a federal consumer product safety standard is in effect, state and local governments do not have the authority to establish or to continue in effect a different safety standard or regulation designed to deal with the same risk of injury as the federal standard. This statutory effect on state and local government regulations, known as preemption, applies where there is a consumer product safety standard in effect. The statutory preemption provision would not take effect if the Commission issued a final disclosure requirement under section 27(e), since the disclosure requirement would not be a consumer product safety standard issued under sections 7 and 9 of the act (15 U.S.C. 2056, 2058). Interested persons should be aware, however, that even though the statutory preemption provision would not apply, there may be some instances where certain state or local government actions could be preempted under other legal principles.

K. Specific Questions for Commentors

The Commission is interested in receiving written comments from interested persons on all issues related to this proceeding. The Commission is especially interested in receiving comments addressing the following issues:

(1) Whether there is scientific and medical substantiation for additional reactions to U.F. foam insulation that have been reported in consumer complaints. These reactions include chest pain, cardiac arrythmia, loss of voice, swollen glands, high blood pressure, loss of memory, nosebleeds, and gastrointestinal disturbances. In considering this issue, commentors should also address the issue whether there is sufficient substantiation to support the inclusion of these reactions in the disclosure requirement.

(2) Whether the disclosure requirement would be effective in helping the Commission to carry out the purposes of the act of protecting the public against unreasonable risks of injury associated with consumer products and assisting consumers in evaluating the comparative safety of home insulation materials.

(3) Whether the application of the regulation should be extended to include notification to prospective purchasers of the product for installation in commercial buildings, recreational facilities, schools, and other public buildings where consumers may be exposed to formaldehyde gas released from the product.

Whether the application of the regulation should be extended to include notification to prosective purchasers and purchasers of the products for installation in new homes; and, if so, whether there is an effective means of accomplishing this under the notification provisions of section 27(e) of the act.

(5) Whether the written notification should also be presented in the fact sheet which would be required by the FTC's trade regulation rule for the labeling and advertising of home insulation (16 CFR Part 460, 44 FR 50218, August 27, 1979). This fact sheet must be shown to consumers before they purchase the insulation.

(6) What the economic effect of the proposed rule will be, including the effect of the proposed rule on the price, utility, and availability of the product.

Whether the proposed effective date of six weeks after publication of a final regulation would allow manufacturers sufficient time to design, order, and distribute written notifications complying with the requirements of the proposal.

L. Penalites

If the Commission issues a final regulation requiring the written notification proposed here, manufacturers of U.F. foam insulation must comply with the requirements of the regulation on the effective date. Failure to comply with the regulation is a prohibited act, as specified in section 19(a)(9) of the CPSA, and could lead to civil and criminal penalties under sections 20 and 21 of the CPSA. Section 21 provides criminal penalties consisting of fines of not more than $50,000 and imprisonment for not more than one year. Section 20 provides a maximum civil penalty of $500,000 for any related series of violations. In addition, section 22 of the act authorizes the Commission to obtain an injunction from a United States district court to restrain a violation of the notification requirement.

M. Statutory Findings

Section 27(e) of the Consumer Product Safety Act authorizes the Commission to require manufacturers of consumer products to give notification of performance and technical data related to performance and safety at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale, as necessary to carry out the purposes of the act. As provided in section 2(b) of the CPSA (15 U.S.C. 2051(b)) one purpose of the act is to protect the public against unreasonable risks of injury associated with consumer products. Another purpose of the act is to assist consumers in evaluating the comparative safety of consumer products.

(a) *Protecting the Public.* The Commission has considered the available technical information concerning the physical characteristics of U.F. foam insulation. The information, as discussed in section C of this preamble, shows that U.F. foam insulation can release a measurable amount of formaldehyde after it is manufactured and that U.F. foam insulation may release formaldehyde gas into the home for an indefinite period of time after installation. This information, along with information available from the Commission's investigation of consumer complaints, also shows that in some instances, inexpensive remedial measures, short of removing the insulation product from the home, are not effective in adequately controlling the release into the home of formaldehyde gas from the product.

As discussed in section D(1) of this preamble the Commission has also examined available information concerning consumer complaints. This information shows that there have been over 1000 consumer complaints of adverse health effects from the release of formaldehyde gas from U.F. foam insulation. Based on in-depth investigations of some of these complaints, the Commission believes that consumers have suffered illnesses as a result of the product, and have been hospitalized, and in some cases forced to vacate their homes. Based on this information and other available medical and scientific information described in section D(2) of this preamble, the Commission believes that exposure to formaldehyde gas can produce serious illnesses in humans. The symptoms of these illnesses include eye, nose, and throat irritation, coughing, shortness of breath, skin irritation, nausea, headaches, and dizziness. Since some of the symptoms are flu-like, many consumers may not associate these symptoms with the insulation product. In addition, persons who have a history of respiratory problems or allergies, especially persons who are allergic to formaldehyde, may suffer more serious reactions.

In section E of this preamble, the Commission has explained why it believes the proposed regulation is necessary and how the proposed regulation would assist the Commission in protecting the public.

As discussed in section F of the preamble, the Commission has also examined the potential economic impact of requiring a written notification to reduce the risk of injury associated with the potential release of formaldehyde gas from U.F. foam insulation. The Commission believes that the proposed regulation may have a minor impact on the price and availability of the product and would result in a greater average utility of the product.

As a result of the risk injury associated with U.F. foam insulation because of the potential release of formaldehyde gas from the product, the minor impact that the proposed regulation may have on the price, and availability of the product, along with the likely increase in average utility of the product, the Commission preliminarily determines that there is an unreasonable risk of injury associated with U.F. foam insulation that is sold by manufacturers without the written notification that would be required by Part 1405.

The Commission preliminarily determines that, in order to carry out the purpose of the CPSA of protecting the public against unreasonable risks of injury, it is necessary to require manufacturers of U.F. foam insulation to provide the written notification required by proposed Part 1405 as set forth below.

(b) *Assisting purchasers in evaluating the comparative safety of home insulation products.* As discussed in section E of this preamble, the data before the Commission indicate that many consumers may be unaware of the information in the proposed written notification at the time they purchase the product. Many manufacturers have not provided consumers with all of the information in the proposed written notification, or may not have provided the information in a uniform manner.

Other types of common home insulation materials, such as mineral wool (including fibrous glass) and cellulose insulation, have not been shown to present the same risk of injury from the potential release of formaldehyde gas as does U.F. foam insulation. These other types of insulation, however, do have safety-related information on their containers. Members of the mineral wool insulation industry have voluntarily agreed to label their product to address, among other things, clearance around heat sources and proper installation of insulation with flammable vapor barriers. The Commission has issued a disclosure requirement for cellulose insulation at 16 CFR Part 1404 that requires cellulose insulation to be properly labeled to avoid the unreasonable risk of injury from fire presented by improperly installed cellulose insulation (July 6, 1979, 44 FR 39993).

At the present time, the Commission believes that if there is no mandatory written notification for U.F. foam insulation, it is unlikely that consumers will be given sufficient accurate safety-related information concerning the potential for injury from the release of formaldehyde gas from the product. Without this information, the Commission believes that it would be difficult for consumers to evaluate the safety of U.F. foam insulation in comparison to the safety of other types of home insulation materials. The written notification requirement proposed here would ensure that prospective purchasers and purchasers receive accurate safety-related information that could be used by consumers in comparing U.F. foam insulation with other types of home insulation and in evaluating safety aspects of the types of insulation materials that are available for purchase. Based on presently available information, the Commission has preliminarily determined that the information in the written notification proposed here is necessary to assist consumers in evaluating the comparative safety of U.F. foam insulation in relation to other home insulation products.

N. Conclusion and Proposal

On the basis of the information discussed above, the Commission concludes that a regulation, applicable to manufacturers of U.F. foam insulation, that would require manufacturers to provide a written notification to prospective purchasers and to the first purchaser for purposes other than resale concerning safety related aspects associated with the release of formaldehyde from the product is required to carry out the purposes of the act of: (1) protecting the public against unreasonable risks of injury associated with consumer products and (2) assisting consumers in evaluating the comparative safety of consumer products.

Therefore, under provisions of the Consumer Product Safety Act (secs. 2, 27(e), Pub. L. 92–573, 86 Stat. 1207, 1228; 15 U.S.C. 2051, 2076(e)), the Commission proposes that Title 16, Chapter II of the Code of Federal Regulations be amended by adding to Subchapter B a new Part 1405 as follows:

PART 1405—UREA-FORMALDEHYDE FOAM INSULATION—NOTIFICATION OF PERFORMANCE AND TECHNICAL DATA

Sec.

1405.1 Scope, application, and effective date.
1405.2 Background.
1405.3 Definitions.
1405.4 Requirements to provide performance and technical data by written notice to prospective purchasers and purchasers.

Authority: Section 2, 27, Pub. L. 92–573, 86 Stat. 1207, 1228 (15 U.S.C. 2051, 2076).

§ 1405.1 Scope, application, and effective date.

(a) *Scope and application.* This Part 1405 requires manufacturers of urea-formaldehyde (U.F.) foam insulation to provide a specified notification to consumers who are prospective purchasers and first purchasers of the product for installation in residences. The notification statement in § 1405.4(b) is intended to provide consumers with specified technical and performance information related to the safety of the product before the insulation is installed. The notification informs consumers about the possible adverse effects of release of formaldeyhyde gas from the insulation after it is installed in residences.

(b) *Effective date.* Manufacturers of U.F. foam insulation who present contracts of sale or who make sales to consumers six weeks after publication of a final regulation, for installation of the product in residences, must provide the written notification specified in this regulation.

§ 1405.2 Background.

(a) Based on laboratory research and measurements taken in some homes, the Consumer Product Safety Commission has determined that U.F. foam insulation may release formaldehyde gas into residences in which it is installed. The release of formaldehyde may continue long after the product is installed.

(b) Complaints of incidents received by the Commission and other medical and scientific information indicate that exposure to formaldehyde gas from U.F. foam insulation can produce serious illness in humans, with reactions such as eye, nose, and throat irritation, coughing, shortness or breath, skin irritation, nausea, headaches and dizziness. The symptoms may not appear immediately after the product is installed. Persons with respiratory problems or allergies, especially persons who are allergic to formaldehyde, may suffer more serious reactions.

(c) In those cases where the product has released formaldehyde into the residence, the Commission has information showing that in some instances the formaldehyde gas cannot be controlled by ventilation or other inexpensive means. The Commission also has information showing that use of the insulation in attics, ceilings, or interior walls increases the likelihood of releasing formaldehyde gas into the residence.

(d) After having considered the risk of injury associated with U.F. foam insulation because of the potential release of formaldehyde gas and the impact of the regulation on the price, utility, and availability of the product, the Commission has determined that there is an unreasonable risk of injury associated with U.F. foam insulation that is sold by manufacturers without the written notification at § 1405.4(b). The Commission has determined that disclosure of the information at § 1405.4(b) is necessary to help the Commission in carrying out the purposes of the Consumer Product Safety Act of helping to protect the public against unreasonable risks of injury associated with consumer products and assisting consumers in evaluating the comparative safety of consumer products.

§ 1405.3 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this Part 1405.

(b) "Urea-formaldehyde (U.F.) foam insultation", also referred to as urea-based foam insulation, or foamed-in-place insulation, is a cellular plastic product that is manufactured at the job-site by mixing two liquid chemicals—urea-formaldehyde based (or urea-based) resin and a foaming agent—and, generally, pressurized air, through a foaming equipment system. The resultant mix has a shaving cream-like consistency and is usually pumped through relatively small holes into the walls of standing structures. After it is in the wall, the product cures and becomes firm or self-supporting.

(c) The "manufacturer of U.F. foam insulation" is the installer who combines the component materials and foams the insulation into its permanent location.

§ 1405.4 Requirements to provide performance and technical data by written notice to prospective purchasers and purchasers.

(a) Before the U.F. foam insulation is installed, manufacturers of U.F. foam insulation shall give notification of performance and technical data related to performance and safety: (1) to prospective purchasers of such products at the time of original purchase, and (2) to the first purchaser of such products, for purposes other than resale. Manufacturers of U.F. foam insulation shall include the statement in § 1405.4(b) on all contracts of sale for U.F. foam insulation. If the manufacturer does not present a written contract of sale to the prospective purchaser or purchaser, then the notice shall appear on a receipt of the transaction or on a document relating to a credit transaction involving the sale of U.F. foam insulation that gives the seller a security interest in the consumer's real property. If the manufacturer does not present any of these documents, then the notice shall appear on a separate piece of paper.

(b) The notice shall read as follows:

SAFETY INFORMATION

- THIS PRODUCT MAY RELEASE FORMALDEHYDE GAS INTO YOUR HOME OVER A LONG PERIOD OF TIME.
- FORMALDEHYDE GAS MAY CAUSE EYE, NOSE, AND THROAT IRRITATION, COUGHING, SHORTNESS OF BREATH, SKIN IRRITATION, NAUSEA, HEADACHES AND DIZZINESS. PEOPLE WITH RESPIRATORY PROBLEMS OR ALLERGIES MAY SUFFER MORE SERIOUS REACTIONS, ESPECIALLY PERSONS ALLERGIC TO FORMALDEHYDE.
- The symptoms may appear immediately, or not until months after installation.
- Use of the insulation in attics, ceilings, and interior walls increases the likelihood of releasing formaldehyde gas into your home. In some instances the formaldehyde gas cannot be controlled by ventilation or other inexpensive means.
- If you have health concerns, call your doctor. Also, contact (installer-phone) or (material supplier-phone) immediately.

The U.S. Consumer Product Safety Commission requires the above notice of performance and technical information related to safety.

(c) The notice shall appear prominently and conspicuously. If the contract of sale, receipt, document related to a credit transaction, or separate piece of paper provides for a signature of the purchase, then the notice shall appear on the same page as the signature of the purchaser and before the signature of the purchaser.

(d) The phrase "Safety Information" shall appear in bold face capital letters in a type size of at least 18 points, and shall have a height of at least 0.18 inches. The following three sentences shall appear in bold face capital letters in a type size of at least 10 points, and shall have a height of at least 0.10 inches. The remainder of the statement shall be set in capital and lower case letters in a type size of at least 8 points, having capital letters at least 0.08 inches in height. The notice shall be printed with legible type in a color which contrasts with the background on which the statement is printed. The entire statement, with the exception of the last sentence, shall be enclosed within a ruled rectangle.

To meet the requirement of this section, manufacturers may use any type of written notice, including one which is pressure-sensitive or glued on, provided the notice is made in such a manner that it will remain attached to the contract of sale, receipt, document related to a credit transaction, or separate piece of paper.

(f) The manufacturer shall not be deemed to have met the requirements of this section if the manufacturer provides the prospective purchaser or purchaser with any oral or written statement that in any manner negates or disclaims the notification required by this section.

Interested persons are invited to submit written data, views, or arguments regarding any aspect of proposed Part 1405 on or before August 11, 1980. Comments submitted after this date will be considered to the extent practicable.

Comments must be accompanied, to the extent possible, by supporting data or documentation. Requests for confidentiality of documentation will be handled in accordance with the Freedom of Information Act as amended (5 U.S.C. 552), the Commission's regulations under that act (16 CFR Part 1015), and the provisions of section 6(a)(2) of the CPSA (15 U.S.C. 2055(a)(2)).

Written submissions and any accompanying data or material should be submitted, preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

All written comments that are received, and all other material which the Commission has that is relevant to this proceeding may be seen in, or copies obtained from, the Office of the Secretary, Third floor, 1111 18th Street N.W., Washington, D.C. 20207.

Dated: June 4, 1980.

Sadye E. Dunn,

Consumer Product Safety Commission.

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